



ASAM American Society of Addiction Medicine

Public Policy Statement on Patient Review and Restriction (PRR) Programs

Background

Patient Review and Restriction (PRR) programs, also known as pharmacy “lock-in” programs, allow payers, including State Medicaid programs and commercial insurers, to curb a beneficiary’s overutilization, and possible misuse, of physician services and/or prescription drugs by restricting the patient to a single designated provider, pharmacy, or both.¹ The federal regulation that authorizes the establishment of these programs within Medicaid gives broad discretion to the states to determine whether and how they are implemented:

If a Medicaid agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services from designated providers only.²

The only federal requirements are that Medicaid programs give patients notice and an opportunity for a hearing, ensure that restricted patients still have reasonable access to Medicaid services, and exempt emergency services from the restriction.³ Since the authorizing federal legislation doesn’t offer specific instructions regarding program design or the definition of excessive use of services, there is significant variation in scope and design among the programs that have been established to date.

As of May 2014, 46 state Medicaid agencies operated PRR programs.⁴ Program design varies widely between states in terms of defining high-risk controlled substance use, the scope of restrictions, and length of program enrollment. For example, states use a wide variety of criteria to determine which Medicaid beneficiaries will be enrolled in their PRR programs, from simple numeric thresholds to extensive criteria lists that include a variety of behaviors indicative of over-utilization. Most states define overutilization of controlled substances based on quantities of prescriptions filled, number of pharmacies visited, and/or number of controlled substance prescribers seen over a certain period of time. Many states use a combination of objective criteria and subjective assessment by PRR program staff to determine client enrollment. Moreover, while most Medicaid programs restrict enrollees to a single pharmacy and a single prescribing physician, others restrict only pharmacy access or tier how enrollees are restricted based on the extent of their overutilization.

PRR programs have been instituted and studied primarily in State Medicaid programs, but several commercial insurers also employ them. However, publicly available information about commercial insurer programs is scarce. Finally, while Medicare has historically been prohibited from instituting PRR programs, federal policymakers have recently proposed granting Medicare Prescription Drug Plans (PDPs) the authority to implement them. To date, PDPs have relied on

the Medicare Overutilization Monitoring System (OMS), which provides plans with quarterly reports that identify patients with excessive or potentially dangerous prescription fills and primarily relies on point of sale quantity restrictions to curb medically unnecessary use.⁵

PRR programs have been proposed as a potential tool in the effort to combat prescription drug misuse, diversion, and overdose deaths, both in state Medicaid programs and by commercial insurers. However, peer-reviewed research on the design and effectiveness of PRR programs is scarce.⁶ Studies to date, which primarily stem from publicly accessible internal Medicaid program evaluations, have demonstrated PRR programs can reduce health plan expenditures,^{7,8} use of controlled substances,^{9,10} or both,^{11,12} but none have linked PRR programs to lower diversion rates, lower rates of substance use disorders, increased engagement in substance use disorder treatment, or reduced overdose deaths among beneficiaries. Accordingly, CDC has called for “more current and robust evaluations of PRR programs to examine impact on health-related outcomes such as hospitalizations and overdose deaths.”¹³

Recommendations:

In the face of scarce evidence that PRR programs are an effective mechanism to combat prescription misuse, diversion and overdose deaths, The American Society of Addiction Medicine urges extreme caution towards their use. ASAM advocates for the focus of care to be on the best outcomes for each individual patient. The implementation of a PRR program relinquishes professional judgement regarding a patient’s health in favor of a bureaucratic, one-size-fits-all approach. The potential for unintended consequences to the patient’s health is high if the circumstances of each unique patient’s clinical needs are not assessed by a trained professional. Furthermore, ASAM is concerned that third-party payers adjudicating which patients should enter PRR programs, may represent an inherently biased system, influenced primarily by financial interests such as reduced health plan expenditures.

As an alternative to PRR programs, ASAM advocates for more support of existing programs known to be effective in combating prescription misuse, diversion and overdose deaths, including increased education for prescribers on the disease of addiction and how it is treated, increased use of state Prescription Drug Monitoring Programs¹⁴, improved FDA regulations and monitoring¹⁵, ready access to naloxone¹⁶, and increased access to treatment for addiction¹⁷. Prevention and treatment are the best interventions to address the opioid epidemic. There is no substitute for the professional judgement of a caring and educated physician who has an existing therapeutic alliance with the patient.

If policymakers and payers proceed with implementing PRR programs, the American Society of Addiction Medicine strongly recommends the following:

- 1. Payers, including Medicaid, Medicare and commercial insurers, who choose to institute patient review and restriction (PRR) programs, design them to encourage behavior change and support recovery rather than as punitive measures.**
 - a. A patient’s prescribing physician(s) should be alerted to the patient’s possible prescription drug misuse and encouraged to perform a comprehensive screening and/or assessment of the patient for a possible substance use disorder.
 - b. If indicated, the patient should be referred for follow-up treatment with a specialist pain and/or substance use disorder treatment provider.

2. **More research is needed to determine the best set of criteria to use for identifying patients for enrollment.**
 - a. A consistent, evidence-based definition of high-risk controlled substance use is needed to target patients at risk.
 - b. More research is also needed to determine whether these programs, and which specific elements of these programs if any, contribute to reduced incidence of substance use disorders, reductions in diversion, and reduced morbidity and mortality from substance use disorders among enrollees.
3. **PRR programs should provide reasonable accommodations to patients to ensure program enrollment and de-enrollment is not overly burdensome, particularly for patients diagnosed with on-going malignant conditions, or those needing acute emergency services.**

Other Considerations:

1. **Payers should encourage their prescribers and pharmacists to check their state prescription drug monitoring program (PDMP) before prescribing or dispensing a controlled substance to any patient.**
 - a. When possible, State Medicaid programs should work to integrate data between their PDMP and Medicaid claims to identify patients who may be circumventing the PRR program to obtain additional prescriptions by paying out of pocket. Such an interchange of information may help identify patients in need of substance use disorder education or referral to treatment.
2. **Physicians and all other health professionals licensed to prescribe, dispense or administer prescription medications should be required to obtain training on the use of controlled substances. At a minimum, education should include:**
 - a. The general principles of prescribing medications that are commonly associated with misuse, diversion, and addiction.
 - b. The recognition of addiction, assessment of the risk potential for the development of addiction, and referral to appropriate addiction treatment colleagues when addiction is identified or strongly suspected to be present.
 - c. How health professionals can provide education to patients about the potential harms associated with the use of controlled substances and about the safe storage of and disposal of supplies of controlled substances.
 - d. Guidance on how to use and interpret a prescription drug monitoring database and a urine toxicology screen.

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statements of ASAM are revised on a regular basis; therefore, those wishing to utilize this document must ensure that it is the most current position of ASAM on the topic addressed.

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¹ Centers for Disease Control and Prevention. Patient Review & Restriction Programs: Lessons learned from state Medicaid programs. CDC Expert Panel Meeting Report. August 27-28, 2012. Available at:

http://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf

² 42 CFR 431.54(e)

³ 42 CFR 431.54(e)(1)–(3)

⁴ Roberts, A.W. and Skinner, A.C. Assessing the Present State and Potential of Medicaid Controlled Substance Lock-In Programs. *J Manag Care Pharm.* 2014;20(5):439-46

⁵ Tudor, CG. Medicare Part D Overutilization Monitoring System. CMS Letter to All Part D Sponsors, July 5, 2013.

Available at: [https://www.cms.gov/Medicare/Prescription-Drug-](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMS-memo-Medicare-Part-D-Overutilization-Monitoring-System-07-05-13-.pdf)

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⁶ Roberts, A.W. and Skinner, A.C. Assessing the Present State and Potential of Medicaid Controlled Substance Lock-In Programs. *J Manag Care Pharm.* 2014;20(5):439-46

⁷ Singleton TE. Missouri's lock-in: Control of recipient misutilization. *J Med Manage* 1997;1:10–17.

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¹² Blake SG. Drug expenditures: The effect of the Louisiana Medicaid lock-in on prescription drug utilization and expenditures. *Drug Benefit Trends.* March, 1999.

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http://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf

¹⁴ Centers for Disease Control and Prevention, Injury Prevention and Control: Prescription Drug Overdose. (2015). *What States Need to Know about PDMPs.* Atlanta, GA: Centers for Disease Control and Prevention. Available at

<http://www.cdc.gov/drugoverdose/pdmp/states.html>

¹⁵ American College of Physicians. *Improving FDA Regulation of Prescription Drugs.* Philadelphia: American College of Physicians; 2009: Policy Monograph. (Available from American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106.)

¹⁶ Centers for Disease Control and Prevention. *Community-Based Opioid Overdose Prevention Programs Providing Naloxone – United States, 2010.* *MMWR* 2012;61:101-104

¹⁷ American Society of Addiction Medicine, Treatment Research Institute. (2013). *FDA Approved Medications for the Treatment of Opiate Dependence: Literature Reviews on Effectiveness and Cost-Effectiveness.* Chevy Chase, MD: American Society of Addiction Medicine. Available at

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